

Structured Product Labeling (SPL) OTC Sub-team Teleconference

May 18, 2009, 1:00 – 2:00 pm ET


Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or if you are listed and were not on the call) should notify Marcia Howard.

-  Cheryl Blik, Teva Pharmaceuticals, USA
-  Louise Chartier, W.F. Young
-  Sue Crain, Watson Co.
-  Shelia Dy Juanco, Medline Industries, Inc.
-  Mary Beth Fritz, Prestige Brands Holdings, Inc.
-  Virginia Hogan, Teva Pharmaceuticals, USA
-  Carolyn Lindsay, Cardinal Health
-  John Lorenc, Reed Technology and Information Services, Inc.
-  Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team co-leader)
-  Devon Morgan, Perrigo Company (sub-team co-leader)
-  Priscilla Mott, Johnson & Johnson Consumer & Personal Products Worldwide
-  Janet Riffitts, McNeil Consumer Healthcare
-  Nick Romano, Novartis Consumer Healthcare
-  Gary Saner, Reed Technology and Information Services, Inc.
-  David Schilling, Chattem, Inc.
-  Howard Shatz, Data Conversion Laboratories, Inc.
-  Siobhan Stevens-Miles, Merck & Co., Inc.
-  Karen Stith, Image Solutions
-  Carl Strotz, Wyeth Consumer Healthcare

 Beth Thompson, Medline Industries, Inc.

 Craig Trautman, Intagras

 Mark Vranich, Blistex, Inc.

 Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: June 1, 2009 (will be brief call if no agenda items)

III. FDA Data Council

A. Updates to Data Council Web Pages (as of May 11, 2009) – Please <http://www.fda.gov/oc/datacouncil/> for the latest information.

Interested parties can sign up to receive automatic updates whenever the website is updated directly from the agency (link on the main Data Council page). Although efforts to keep sub-team members informed of updates to the Data Council page, members are encouraged to visit the site periodically to ensure important information is not overlooked. Devon Morgan (Perrigo) noted that the UNII codes are being updated more and more frequently as companies do electronic submissions, so sub-team members may want to pay close attention to the UNII list especially as the June 1, 2009, deadline approaches.

1. UNII list with synonyms
<http://www.fda.gov/oc/datacouncil/UNIIs.zip>

2. XML terminology files with only preferred terms for substances and UNIIs
http://www.fda.gov/oc/datacouncil/terminology_lists.zip

- B. “Validators” webpage (validation tool that can be used to validate SPL Release 4 documents prior to submission to the FDA)
<http://www.fda.gov/oc/datacouncil/validate.html>

The validator should catch the majority of possible errors (~ 90-95%) prior to submissions to FDA but complete validation will not occur until the documents are transmitted via the Electronic Submission Gateway (ESG). This is because there are certain databases which will not be made publicly available therefore it is impossible to validate the pre-submission against this data.

Several members of the sub-team indicated the validator was a useful tool that catches most of the common errors. Howard Shatz (Data Conversion Laboratory) advised team members that if test submissions are completed on XML files alone, an error message will result due to the image file names. If the test submission is completed in a SPL file that also contains images, this error message may be avoided.

IV. Open Discussion by Sub-team Members

Q1. Question to the FDA – **What type of customer support services will FDA have in place by the June 1, 2009, implementation deadline for OTC and Vet Med products?** There is a concern that both FDA and industry will be inundated with questions due to potential submission/transmission problems or lack of familiarity with the electronic submission process.

Sub-team members are encouraged to send any questions or discussion topics for the next call to Paula Markert (GSK), Devon Morgan (Perrigo) and Marcia Howard (CHPA) at their convenience.

V. Upcoming SPL Educational Forums

- A. FDA face-to-face meeting on May 21, 2009 (closed for registration) and June 10, 2009 (attendance will be limited to available seats)

There are openings still available for the June 10, 2009, face-to-face meeting. At this time, no additional in-person meetings are scheduled so sub-team members are encouraged to take advantage of the June meeting if interested.

B. FDA SPL R4 Training Session 9 (webinars)

C. DIA SPL Workshop (August 11-12, 2009, Philadelphia, PA)

As previously indicated, there will be an SPL tutorial offered on the first day of the meeting followed by a second day of “hot topics”, early lessons learned, etc. There will be a vendor showcase throughout the meeting for those interested in speaking with potential service providers on location. Planning is still underway so additional details will be given as they become available. Sub-team members are asked to send any ideas for “hot topics” to Paula, Devon, and Marcia Howard for program consideration.

MDH/05-18-09

SPL OTC Sub-team 18 May 2009 051809.doc

Last Revised: May 18, 2009 Sent: May 18, 2009